

ATTORNEY DOCKET NO. WAPH.002.04US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Indu Parikh *et al.*

Serial No.: 10/029,551

Filed: December 20, 2001

Title: Treatment For Diabetes

) Examiner: Wehbe, Anne Marie Sabrina

) Art Unit: 1632

) TRANSMITTAL

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Transmitted herewith are the following documents in the above-identified application:

- ☐ Small entity status of this Application under 37 CFR 1.9 and 1.27 has been established by a Verified Declaration previously submitted.
- ☐ A Verified Declaration of Small Entity Status Under 37 CFR 1.9 and 1.27 is enclosed.
- ☒ Response to Restriction Requirement.

Also enclosed:

- ☒ Return postcard (postage prepaid).

CERTIFICATE OF FIRST CLASS MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

04/23/04
(Date of Deposit)

(Signature)

Mariah Salisbury
(Printed Name)

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The fees have been calculated as shown below:

<u>Claims</u>	<u>Prev.</u>	<u>Current</u>	<u>Extra</u>	<u>Small Entity</u>	<u>Large Entity</u>
Total:	32	25	0	x \$9 = \$0.00	x \$18 = \$0.00
Indep:	8	6	0	x \$43 = \$0.00	x \$86 = \$0.00
Mult:	y	y		\$0.00	\$0.00

Total Additional Claims Fee: \$ 0.00

Extension of Time Fee	Small Entity	Large Entity
<input type="checkbox"/> One Month	\$ 55.00	\$ 110.00
<input type="checkbox"/> Two Months	\$210.00	\$ 420.00
<input type="checkbox"/> Three Months	\$475.00	\$ 950.00
<input type="checkbox"/> Four Months	\$740.00	\$1480.00
<input type="checkbox"/> Five Months	\$1,005.00	\$2,010.00

Total Extension of Time Fee: \$ 0.00

Other fees (list individually):

Total Other Fees: \$ 0.00**Terminal Disclaimer / 37 CFR 1.20(d) \$ 0.00****TOTAL FEES: \$ 0.00**

- ☐ A credit card authorization for the amount of the above-indicated TOTAL FEES is attached.
- ☐ Please charge Deposit Account No. 18-0020 in the amount of the above-indicated TOTAL FEES.
- ☒ No fee is required.

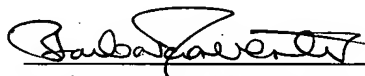
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- [X] Conditional Petition for Extension of Time: An extension of time is requested in the present and/or the above-referenced parent application to provide for timely filing if an extension of time is still required after all papers filed with this transmittal have been considered.
- [X] The Commissioner is hereby authorized to charge any underpayment of the following fees associated with this communication, including any necessary fees for extension of time, or credit any overpayment to Deposit Account No. 18-0020.
- [X] Any filing fees under 37 CFR 1.16 for the presentation of extra claims.
- [X] Any parent application processing fees under 37 CFR 1.17.
- [X] A duplicate copy of this sheet is attached for accounting purposes.

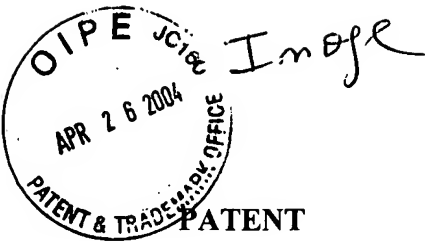
Respectfully submitted,

Dated: April 23, 2004


Barbara Rae-Venter, Ph.D.
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Indu Parikh <i>et al.</i>) Examiner: Wehbe, Anne Marie Sabrina
)
Serial No.: 10/029,551) Art Unit: 1632
)
Filed: December 20, 2001)
)
Title: Treatment For Diabetes) <u>RESPONSE TO RESTRICTION</u>
) <u>REQUIREMENT</u>
)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is in response to the Restriction Requirement mailed March 23, 2004. Please amend the above-identified application as follows:

- Restriction Requirement** begins on page 2 of this paper
- Response to Restriction Requirement** begins on page 3 of this paper.
- Traversal of Restriction Requirement** begins on page 4 of this paper
- Amendments to the Claims** are reflected in the listing of claims which begins on page 6 of this paper.
- Remarks/Conclusion** begin on page 10 of this paper.

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04/23/04
(Date of Deposit)

(Signature)
Mariah Salisbury
(Printed Name)

Restriction Requirement:

The Examiner has required restriction to one of the following inventions:

- Group I: Claims 1-3, 19, and 23 drawn to methods of treating diabetes by administering a gastrin/CCK receptor ligand and an EGF receptor ligand, classified in class 514, subclass 2
- Group II: Claims 4-7, 20, 25-27, and 34-35, drawn to methods of transplanting mature insulin-secreting beta-cells, classified in class 424, subclass 93.1.
- Group III: Claims 20-22, 24, 28-29, and 34-35, drawn to methods for obtaining an expanded population of insulin secreting beta cells ex vivo, classified in class 435, subclasses 325 and 395.
- Group IV: Claims 30-33, drawn to kits comprising a gastrin/CCK receptor ligand and an EGF receptor ligand, classified in class 530, subclass 350.
- Group V: Claims 36-37, drawn to methods of administering a compound that increases the secretion of an endogenous gastrin or cholecystokinin, classified in class 424, subclass 600.

1. Response to Restriction Requirement.

Applicants hereby elect Group IV (Claims 30-33) with traverse.

2. Traversal of Restriction Requirement.

Applicants traverse the Restriction Requirement because both criteria for a proper requirement for restriction have not been met for some of the Groups, namely (1) that the inventions must be independent or distinct as claimed and (2) there must be a serious burden on the Examiner if restriction is required (MPEP section 803). Applicants do not disagree with the Examiner's finding of four independent or distinct inventions however in Applicants opinion it would not constitute a serious burden on the Examiner to examine some of the Groups together as set forth below, in particular Group IV and Group III and/or Group I.

Applicants have elected Group IV (Claims 30-33), drawn to kits comprising a gastrin/CCK receptor ligand and an EGF receptor ligand, classified in class 530, subclass 350. These claims are novel and unobvious because the pharmaceutical composition comprising a gastrin/CCK receptor ligand and an EGF receptor ligand, and a pharmaceutically acceptable carrier is patented (see USPN 6,288,301, Claim 7). The claims of Group III (Claims 20-22, 24, 28-29, and 34-35) are drawn to methods for obtaining an expanded population of insulin secreting beta cells ex vivo, classified in class 435, subclasses 325 and 395, using the patented composition. It therefore would not constitute an undue burden on the Examiner to examine these claims together since claims of Group III are methods of using a patented compound and therefore are themselves novel and unobvious.

The claims of Group I (Claims 1-3, 19, and 23) are drawn to methods of treating diabetes by administering a gastrin/CCK receptor ligand and an EGF receptor ligand, classified in class 514, subclass 2. Again, it would not constitute an undue burden on the Examiner to examine these claims together with those of Group IV since the claims of Group I are methods of using a patented compound and therefore are themselves novel and unobvious.

For the above reasons, the Examiner is respectfully requested to withdraw the restriction

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requirement as to Groups IV and III and/or Groups IV and I and examine the claims of these Groups together.